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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE INSULIN PRICING LITIGATION	Civil Action No. 17-699(BRM)(LHG) **ORAL ARGUMENT REQUESTED**

DEFENDANTS' REPLY IN FURTHER SUPPORT OF MOTION TO DISMISS THE FIRST AMENDED COMPLAINT

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PRELIMINARY STATEMENT

Plaintiffs' opposition to the motion to dismiss confirms the motion's essential premise: that plaintiffs lack a coherent theory—let alone one supported by factual allegations—that defendants defrauded *anyone*. Plaintiffs fail to identify any affirmative representation, by any defendant, conveying anything remotely deceptive. And they expressly abandon any claim of a fraudulent omission.

Defendants' moving brief showed that plaintiffs are seeking to use criminal fraud statutes to regulate the payment of rebates, a common feature of competitive prescription drug markets that private and public health insurers use to reduce their drug costs. And plaintiffs' opposition fails to articulate any principle that would distinguish the rebates challenged here from all others in this industry and other competitive markets.

Instead, plaintiffs attempt to transform this case into an updated version of decades-old drug-pricing litigation brought by these same lawyers. But plaintiffs' counsel should know that the allegations there differed fundamentally from those here. In the prior cases, the defendant manufacturers reported "Average Wholesale Prices" ("AWPs") that were literally false because they had no relationship to the average wholesale prices that pharmacies and physicians actually paid for the drugs.

Plaintiffs do not (and cannot) allege any such fraud here. In fact, plaintiffs' theory that defendants' list prices are fraudulent fails because plaintiffs concede that those list prices reflect real prices that are actually charged to wholesalers and pharmacies. Plaintiffs nonetheless contend that the list prices are fraudulent because they do not approximate the net revenues that defendants realize after paying rebates to PBMs and insurers—which plaintiffs call "net prices." But defendants have *never* claimed that their list prices reflect their net prices. Plaintiffs do not identify a single such representation. To the contrary, plaintiffs refer only to statements in which defendants have expressly disclosed the *opposite*: namely, that rebates *lower* their net prices and *offset* list price increases.

Thus, plaintiffs' entire case rests not on any misrepresentation, but on a policy proposal: that there should be little difference between the prices manufacturers actually charge and the revenue that they realize after paying rebates to PBMs and insurers. This is a plea for judicial regulation of pharmaceutical pricing masquerading as a fraud claim. Allowing the case to proceed would transform this Court into a regulator of pharmaceutical prices and rebates, with no reason to believe that the requested regulations would benefit consumers. Because plaintiffs' unsubstantiated and unworkable theory of fraud permeates all of their causes of action, under the federal RICO statute and a host of state laws, the complaint should be dismissed in its entirety.

In any event, plaintiffs' RICO claims are barred as a matter of law by binding precedent. Plaintiffs concede that they are not the first party to pay the prices set by defendants. This concession entirely disposes of plaintiffs' RICO claims, as the Third Circuit has expressly held that indirect purchasers cannot assert claims under the RICO statute. Because the indirect purchaser rule is an "absolute bar" to plaintiffs' RICO claims, the Court should dismiss them on that ground alone. In addition, plaintiffs' claims suffer from a host of other defects:

- Plaintiffs have not pleaded—given the fundamental absence of fraud—a cognizable pattern of racketeering activity.
- Plaintiffs have not pleaded a valid RICO enterprise because they have effectively conceded that the members of each putative enterprise did not share a "common purpose," and they do not plausibly allege that defendants conducted the affairs of each supposed enterprise.
- Plaintiffs admit that other entities in the distribution chain—the insurers and pharmacies that actually set consumers' out-of-pocket prices—knew of the supposed fraud, and so plaintiffs cannot show that defendants' conduct proximately caused their alleged injuries as RICO requires.
- Plaintiffs postulate a new theory for their RICO conspiracy claim, but it does not appear in their complaint and is not substantiated with any plausible allegations of a conspiratorial agreement.
- Plaintiffs have alleged neither "unlawful conduct" nor any "ascertainable loss," which are essential elements of their New Jersey Consumer Fraud Act ("NJCFA") claims.

Moreover, all of plaintiffs' other state law claims fail for the same reasons that the RICO claims fail, and because plaintiffs never tie their generic allegations to the particular requirements of each state statute. And many of the state law claims fail for various other reasons, including plaintiffs' lack of standing for

claims under the laws of seventeen states where no plaintiff resides or made a purchase, as well as plaintiffs' failure to meet certain state-specific requirements.

Accordingly, all of plaintiffs' claims should be dismissed. And because plaintiffs collectively have filed no fewer than *seven* complaints against defendants—including an amended version of their consolidated class action complaint, which they filed after defendants' previous motion to dismiss pointed out the numerous defects in their claims—the dismissal should be with prejudice.

ARGUMENT

I. The RICO Claims Should Be Dismissed

A. Plaintiffs' RICO Claims Are Barred by the Indirect Purchaser Rule

Plaintiffs concede that defendants "charge their artificially inflated benchmark prices to distributors" *before* consumers pay for analog insulin. Opp. at 18 n.33.[1] This concession is fatal to plaintiffs' RICO claims. Under the indirect purchaser rule, the fact that plaintiffs are not the first party to pay the benchmark price is an "absolute bar" to any RICO claim. *McCarthy v. Recordex Serv., Inc.*,

[1] "RICO MTD" refers to Defendants' Memorandum of Law in Support of Motion to Dismiss the First Amended Class Action Complaint (Counts 1-5) (Dkt. #158-1), and "Opp." refers to Plaintiffs' Brief in Opposition to Defendants' Motion to Dismiss the First Amended Class Action Complaint (Dkt. #181).

80 F.3d 842, 852 (3d Cir. 1996).[2] Plaintiffs nonetheless insist that their claims are not barred because (1) the indirect purchaser rule does not apply to RICO claims, and (2) defendants' alleged fraud directly injured plaintiffs. Opp. at 30-36. Those arguments lack any merit.

First, the Third Circuit expressly held in *McCarthy* that the indirect purchaser rule governs RICO claims. 80 F.3d at 855 ("[T]he central and dispositive issue [under RICO] is whether plaintiffs are 'direct purchasers.'"). Contrary to this binding precedent, plaintiffs contend that the Supreme Court's prior decision in *Holmes* exempts RICO claims from the rule. Opp. at 31-32.[3] Plaintiffs have it backwards: *Holmes* held that antitrust standing precedents govern RICO claims because Congress modeled RICO's civil action provision on a

[2] This rule serves the crucial objectives of avoiding "the risk of duplicative recovery and the potential for overly-complex damages and apportionment calculations." *McCarthy*, 80 F.3d at 851 n.14; *see also*, *e.g.*, *Holmes v. SIPC*, 503 U.S. 258, 269 (1992); *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 459-60 (2006). Plaintiffs' claims squarely implicate these concerns. Any price "inflation" would impact wholesalers, pharmacies, and insurers *before* consumers. Ascertaining any injury would thus require tracing the "inflation" through the vast web of contractual relationships among these intermediaries.

[3] Plaintiffs also cite *Bridge v. Phoenix Bond & Indemnity Co.*, 553 U.S. 639 (2008) and *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479 (1985), but those cases are inapposite. This Court has explained that "*Bridge* has little or no bearing on" whether the "'direct purchaser' requirement" applies to RICO claims. *Hale v. Stryker Orthopaedics*, 2009 WL 321579, at *4 (D.N.J. Feb. 9, 2009). *Sedima* addressed the irrelevant question of whether a civil RICO action "can proceed only after a criminal conviction." 473 U.S. at 488.

substantively similar antitrust provision. 503 U.S. at 267-68. The Third Circuit then relied on *Holmes* in concluding that the indirect purchaser rule recognized under antitrust law "appl[ies] equally to allegations of RICO violations." *McCarthy*, 80 F.3d at 855. Other courts of appeals have similarly invoked *Holmes* to hold that the indirect purchaser rule applies to RICO claims. *See Fiala v. B&B Enters.*, 738 F.3d 847, 851 (7th Cir. 2013); *Trollinger v. Tyson Foods, Inc.*, 370 F.3d 602, 616 (6th Cir. 2004).

Second, in attempting to evade the indirect purchaser rule by arguing that they "pay prices *directly* based on" benchmark prices (Opp. at 32), plaintiffs ignore the prior transactions (described in their own complaint) between intermediaries in the supply chain:

- Defendants first sell analog insulin to wholesalers at prices "based on the benchmark prices that are set by manufacturers." FAC ¶ 176; *see also id.* ¶ 168; RICO MTD at 8-9; Opp. at 18 n.33.
- Wholesalers then earn a small margin by selling insulin to pharmacies at approximately these benchmark prices. FAC ¶¶ 164, 167-168; *see also* RICO MTD at 9.
- Finally, pharmacies earn a margin by charging benchmark-based prices. FAC ¶¶ 179, 181, 201. These "point of sale prices" are set by bargaining between the pharmacy and PBMs (for insured consumers) or unilaterally by the pharmacy (for uninsured consumers). RICO MTD at 10-11 & n.8; Opp. at 8.

Thus, defendants do not "directly" set the prices paid by consumers; rather, those prices are determined by intermediaries in the distribution chain who impose their own markups over the prices they pay. To the extent that consumer prices

relate to allegedly inflated benchmark prices (Opp. at 32), it is because those benchmark-based prices are passed through from wholesaler to pharmacy to consumer on terms set by those entities—not by defendants. Plaintiffs' contention that they have not alleged a "pass through" of an inflated price is thus demonstrably incorrect.

Even if defendants' benchmark prices *did* "directly" affect the prices paid by consumers (Opp. at 32), plaintiffs would still lack standing under RICO. The indirect purchaser rule applies even when overcharges paid by consumers are "dollar for dollar" the same as those paid by intermediaries. *McCarthy*, 80 F.3d at 853. Indeed, a long line of cases holds that the indirect purchaser rule prohibits consumers from suing drug manufacturers for artificially inflated prices even if consumers "had borne the full brunt of the injuries." *Warren Gen. Hosp. v. Amgen Inc.*, 643 F.3d 77, 92 (3d Cir. 2011); *see also* RICO MTD at 29 (collecting cases).[4]

This conclusion is underscored by *Hale*, in which this Court rejected the argument that the plaintiffs "pled direct injury since they paid artificially-inflated coinsurance payments." 2009 WL 321579, at *4. Judge Martini held that the coinsurance payments, which were allegedly inflated because intermediaries had

[4] Plaintiffs summarily dismiss these cases as "antitrust decisions" (Opp. at 34 n.92), again refusing to accept that the indirect purchaser rule first recognized in antitrust cases applies with equal force to RICO claims. RICO MTD at 27-28.

paid allegedly inflated prices for defendants' joint implant devices and passed them through to the plaintiffs, did "not allow [plaintiffs] to stand in the shoes of a direct purchaser for standing purposes." *Id.* Plaintiffs' efforts to distinguish *Hale* fall flat. Opp. at 34. The complaint in *Hale* alleged that the manufacturers' "kickback scheme" increased costs to the plaintiffs "in the form of an elevated coinsurance payment." 2009 WL 321579, at *1. These allegations are virtually identical to plaintiffs' claims against defendants here. FAC ¶ 211 ("When the defendants inflate benchmark prices so that they can offer PBMs larger spreads, they harm . . . insured consumers paying coinsurance.").

Nor can plaintiffs avoid the indirect purchaser rule by invoking *In re Avandia Marketing, Sales Practices & Product Liability Litigation*, 804 F.3d 633 (3d Cir. 2015). *Avandia* did not address the rule because it was not implicated in that case. In *Avandia*, the plaintiff health plans alleged that the defendant manufacturer misrepresented the safety of a drug (Avandia) *directly* to them, and as a direct result were deceived into "cover[ing] Avandia at favorable rates." 804 F.3d at 636. Wholesalers and pharmacies could not have brought a RICO claim based on those allegations, *because the defendants never directed a misrepresentation to them*. Here, by contrast, plaintiffs allege that defendants' "artificially inflated list prices" are announced to, and paid by, wholesalers and pharmacies in the first instance, before consumers make their purchases. *Warren*,

643 F.3d at 94-95 (applying the indirect purchaser rule to prescription drug sales because "the possibility that the wholesaler was harmed by defendant's actions exists even if the majority of the injury is borne by the indirect purchaser").[5]

B. Plaintiffs Do Not Plead Facts Amounting to Mail or Wire Fraud

In response to defendants' showing that civil RICO claimants must plead criminal conduct by defendants, plaintiffs concede that criminality is required. RICO MTD at 21; Opp. at 15. Yet plaintiffs have not pleaded any facts constituting criminal mail or wire fraud, the offenses that they identify as RICO predicate acts.

1. Defendants' List Prices Are Real Prices

Plaintiffs' RICO claims rest on the argument that defendants committed criminal fraud by "publishing artificially inflated list prices." Opp. at 3, 16.[6] That argument suffers from a fatal defect: defendants' list prices are *real prices*.

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[5] Plaintiffs' reliance on *Desiano v. Warner-Lambert Co.*, 326 F.3d 339 (2d Cir. 2003) underscores that their claims are blocked by the indirect purchaser rule. The *Desiano* court specifically declined to apply *Holmes*' proximate cause standard because the plaintiffs did not assert a RICO claim. *Id.* at 348. Instead, the court applied state law *lacking* "the relatively narrow directness requirements applied by the federal courts under RICO in *Holmes*." *Id.* at 348-49. By analogizing to a non-RICO case without *Holmes*' "directness requirements," plaintiffs highlight the indirectness of their claims.

[6] Although plaintiffs' complaint uses "benchmark prices" to refer to WACs and AWPs for defendants' insulin products, plaintiffs' brief also describes them as "list prices." *See* FAC ¶ 174; Opp. at 8.

By plaintiffs' own admission, defendants *actually sell* analog insulin to wholesalers at WAC minus small discounts. *See* FAC ¶ 176 ("Prices to wholesalers tend to be based on the benchmark prices that are set by manufacturers or wholesale acquisition costs ('WACs')."). Accordingly, defendants' list prices reflect the *actual prices* at which their customers acquire their products. This plainly distinguishes this case from *Lupron* and *AWP*, in which the plaintiffs' claims were premised on the allegation that the published AWPs for certain drugs bore no reasonable relationship to the prices actually paid by retail providers (pharmacies and physicians) to acquire the drugs. *See infra* at 14-15.[7]

Bound by their own allegations, plaintiffs nonetheless contend that defendants' list prices are "artificial" because they do not reasonably approximate

[7] Plaintiffs' suggestion that the publication of AWPs constitutes a representation *by defendants* is not plausible. RICO MTD at 8-9. Defendants do not set or report AWPs for their analog insulins; rather, AWPs are calculated and published by third-party price reporting companies. In any event, unlike in *Lupron* and *AWP*, the published AWPs for defendants' analog insulins reflect the actual prices paid by pharmacies because (1) wholesalers re-sell analog insulin to pharmacies at approximately WAC, and (2) the third-party price reporting companies calculate the AWPs for defendants' analog insulins as a formulaic markup of 20% over WAC. FAC ¶ 174; Opp. at 8 n.14. Plaintiffs' counsel is well aware that publishers generate AWPs by applying a standard markup to manufacturers' WACs. Indeed, plaintiffs' counsel agreed to settlements requiring publishers to calculate AWP as 120% of WAC. *See New Eng. Carpenters Health Benefits Fund v. First DataBank, Inc.*, 602 F. Supp. 2d 277, 279 (D. Mass.) (requiring publishers to "roll back from 1.25 to 1.20 the [WAC] to AWP mark-up" for affected drugs), *aff'd sub nom. Nat'l Ass'n of Chain Drug Stores v. New Eng. Carpenters Health Benefits Fund*, 582 F.3d 30 (1st Cir. 2009).

the revenue that manufacturers realize after paying PBM rebates, an amount that plaintiffs label the "net price." Opp. at 3, 13. But plaintiffs' complaint concedes that a difference between the list price manufacturers charge wholesalers and the "net price" manufacturers ultimately realize after paying rebates—which arises *whenever* manufacturers pay rebates to PBMs, government programs, or any other payors—does not, by itself, render the list price fraudulent. *See, e.g.*, FAC ¶ 6 (acknowledging "[t]he legitimate use of discounts and rebates").

2. The Complaint Fails to Allege a Misrepresentation or Omission

Plaintiffs are thus left to argue that defendants have engaged in criminal fraud by *affirmatively representing* that their list prices reasonably approximate "net prices." Opp. at 21.[8] As shown below, however, plaintiffs do not identify a single statement by a defendant that its list prices reflect "net prices," and their own allegations demonstrate that defendants have expressly, in public statements, distinguished between list and net prices.

Deploying out-of-context quotations, plaintiffs attempt to write the "scheme to defraud" element out of the mail and wire fraud statutes, and to suggest that criminal fraud is instead defined by nebulous notions of morality. Opp. at 16. But

[8] Plaintiffs have abandoned their theory of fraudulent *omission* by conceding that (1) defendants are "under no legal obligation to disclose . . . the rebates they pay to PBMs" and (2) "[t]his is not a case of omission." Opp. at 17.

plaintiffs ignore the fundamental requirement that a criminal scheme to defraud "must involve some sort of fraudulent misrepresentation or omission." *Lum v. Bank of Am.*, 361 F.3d 217, 223 (3d Cir. 2004); *see also Travelers Indem. Co. v. Cephalon, Inc.*, 620 F. App'x 82, 85-86 (3d Cir. 2015) (Rule 9(b) requires "specific fraudulent statements, omissions, or misrepresentations").

a. Plaintiffs plead no affirmative misrepresentations by defendants regarding their list prices

Plaintiffs appear to concede that defendants have not made any misrepresentations regarding WAC, which is defined by federal statute as a list price to wholesalers *not* including discounts or rebates.[9] Plaintiffs further concede that they "do not allege that Novo and Sanofi misrepresented their AWPs as net prices" or that "defendants misrepresented their AWPs as the lowest prices available." Opp. at 21, 24; *see also id.* at 23 ("defendants did not represent their

[9] Any suggestion that defendants' WACs are fraudulent because they do not reflect PBM rebates is foreclosed by this statutory definition. *See* 42 U.S.C. § 1395w-3a(c)(6)(B); RICO MTD at 8, 33. Plaintiffs label this definition "irrelevant" because it relates to reimbursing "single source drugs" (*i.e.*, drugs without a generic equivalent) under Medicare Part B. Opp. at 21. But defendants' analog insulins *are* single source drugs (FAC ¶ 205), and the WAC for an analog insulin is the same regardless of whether the consumer is insured (under Medicare Part B, Medicare Part D, another government program, or private health plan) or uninsured. When a wholesaler buys analog insulin (FAC ¶¶ 167-168, 174-176), it is not known how *each unit* will be paid for in a *subsequent* retail transaction, so WAC cannot vary based on how or whether consumers are insured.

AWPs to be net prices"). Instead, plaintiffs argue that defendants misrepresented their AWPs as "reasonable approximations of their true prices," *i.e.*, the prices that manufacturers realize after paying rebates to PBMs, and as "reasonable benchmarks for consumer payments." *Id*. at 21.

There is no basis—much less a plausible basis—for that theory. RICO MTD at 18-19, 31-34. Plaintiffs fail to identify *any* statement by a defendant that embodies or even comes close to the "affirmative misrepresentations" that plaintiffs seek to attribute to defendants. *See id*. Under Rule 9(b), which requires plaintiffs to identify "specific fraudulent statements, omissions, or misrepresentations," that failure is fatal to plaintiffs' RICO claims. *See id*. at 21.

Moreover, the specific statements attributed to defendants expressly represent that there is a *difference* between list prices and "net prices." *See*, *e.g.*, FAC ¶ 242 (quoting Novo Nordisk statement that it is "misleading" to focus on its list prices because the "net price" Novo Nordisk realizes after "rebates, fees and other price concessions we provide to the payer . . . more closely reflects our actual profits"); *id.* ¶ 244 (quoting Sanofi statement that the company had "increased the level of rebates granted for Lantus® in order to maintain favorable formulary positions with key payers"). Plaintiffs cannot plausibly claim to have been misled into believing that list prices approximate net prices when they affirmatively allege that defendants have explicitly disclosed the opposite.

b. AWPs for defendants' analog insulin are not "affirmative misrepresentations"

In the face of Rule 9(b), plaintiffs argue that AWPs that do not reasonably approximate "net prices" are themselves fraudulent. *See, e.g.*, Opp. at 17 ("[T]he defendants held [AWPs] out as ['Average Wholesale Prices'] through publication of the prices. This is the misrepresentation for which the plaintiffs seek recovery.").

Plaintiffs attempt to support that position with decisions from the Average Wholesale Price (AWP) litigation. But those cases refute plaintiffs' theory of fraud. In *Lupron* and *AWP*, the plaintiffs showed that the challenged AWPs were literally false: *Contrary to the plain meaning of the term*, AWPs did not approximate the "average wholesale prices" paid by retail providers (doctors and pharmacies) that sold drugs to consumers. *See*, *e.g.*, *In re Lupron Marketing & Sales Practices Litig.*, 295 F. Supp. 2d 148, 160 (D. Mass. 2003) ("Plaintiffs' core allegation is that the AWPs for Lupron® reported by the defendants bore no resemblance to the actual prices charged . . . to doctors, nor did they bear any relationship to a reasonable interpretation of the terms 'average' or 'wholesale.'"); *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d 277, 285, 287-88 (D. Mass. 2004) (adopting a dictionary definition of "Average Wholesale Price" and holding that it "means the average price at which wholesalers sell drugs

to their customers, including physicians and pharmacies").[10] Instead, the AWPs in those cases dramatically exceeded the actual "average wholesale prices" paid by providers—by 300% in *Lupron*, and by *up to 20,735%* in *AWP*. *Lupron*, 295 F. Supp. 2d at 168 n.19; *AWP*, 263 F. Supp. 2d at 172, 178. The cases thus stand for the proposition that "Average Wholesale Prices" that do not reasonably approximate actual average wholesale prices may constitute fraud.

Here, by contrast, plaintiffs do not dispute that the AWPs for defendants' analog insulin reasonably approximated the average wholesale prices paid by pharmacies. RICO MTD at 8-9. Instead, plaintiffs' theory of criminal fraud rests on the premise that AWPs must approximate an entirely different price point: the "net price" realized by manufacturers after paying PBM rebates. Plaintiffs' theory of fraud is directly *contrary* to the holding of the AWP cases that AWPs should reasonably approximate prices paid by retail providers.

The example drawn from plaintiffs' complaint illustrates this point. RICO MTD at 14; FAC ¶¶ 201-202. Consider a box of analog insulin pens with a WAC of $375.00. The manufacturer sells it to the wholesaler for $367.50 (WAC minus a

[10] *See also In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 178 (D. Mass. 2003) (noting plaintiffs' allegations that the difference between the "actual average wholesale price" and "reported AWP" creates a difference "between the actual cost of a drug to a health care provider, and the reimbursement paid to the provider").

2% prompt payment discount). The wholesaler sells it to a pharmacy for $375.00. After the pharmacy sells the insulin to an insured consumer, the manufacturer pays the consumer's PBM a rebate of $187.50 (50% of WAC). The manufacturer's "net price" is therefore $180.00—the price it charged to the wholesaler ($367.50) minus the rebate it paid to the PBM ($187.50). Under *Lupron* and *AWP*, the AWP should, based on the plain meaning of "Average Wholesale Price," bear a reasonable relationship to the wholesale price paid by the pharmacy: $375.00. But under plaintiffs' newly concocted theory, the AWP should—for some inexplicable reason—approximate the manufacturer's "net price": $180.00. Plaintiffs' theory is fundamentally incompatible with the very cases on which they rely.

Plaintiffs' theory is also incoherent. As plaintiffs acknowledge, the use of AWPs as "price benchmarks" provides "an efficient method" for determining how much insurers and consumers should pay pharmacies at the point of sale. FAC ¶ 177. But if AWPs approximated the manufacturer's "net price" rather than the price paid by pharmacies to acquire the drug, AWPs would no longer provide a useful benchmark for determining how much pharmacies should be reimbursed for a drug, eliminating the very efficiency that plaintiffs tout.[11]

[11] Nor are plaintiffs' claims analogous to claims involving PBMs in the AWP cases, which alleged that PBMs "keep [rebates] without disclosing to the health plans the true amounts of the rebates." *In re Pharm. Indus. Average Wholesale Price Litig.*, 307 F. Supp. 2d 196, 205-06 (D. Mass. 2004). Here, in

The only way to square plaintiffs' theory of misrepresentation with *Lupron* and *AWP* would be to require manufacturers to limit the rebates they pay to PBMs so that AWPs reflect *both* the prices charged to pharmacies *and* the "net price" that manufacturers realize after paying PBM rebates. Indeed, plaintiffs have acknowledged that they are seeking to impose criminal liability on drug manufacturers for paying PBM rebates that exceed 20% of WAC. Opp. at 22.[12] There is no legal support whatsoever for this arbitrary cap on rebates, and the Court should decline plaintiffs' invitation to legislate prices and rebates as a pharmaceutical pricing super-regulator.[13]

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contrast, plaintiffs allege that PBMs (1) "pas[s] on" rebates to their health insurer clients after "tak[ing] a cut," FAC ¶ 204; *see also id.* ¶¶ 4, 169, 170 fig. 3, 201; and (2) "market their ostensibly larger 'rebates' to their plan clients." Opp. at 2. Thus, plaintiffs argue, health insurers are not deceived by higher AWPs and rebates (*id.* at 37), but instead "*benefit*" from them (*id.* at 38).

[12] Plaintiffs argue that they "would not have sued" if AWPs for defendants' analog insulins were no more than 50% greater than defendants' "net prices." Opp. at 22. Because AWP is 120% of WAC, that means net prices could be no lower than 80% of WAC, and rebates could be no greater than 20% of WAC, in order to satisfy plaintiffs' arbitrary 50% limit. In comparison, Medicaid requires minimum rebates of 23.1% of the average price paid by wholesalers. 42 U.S.C. § 1396r–8(c)(1)(B)(i)(VI); 42 C.F.R. § 447.509(a)(1)(i)(B)(3).

[13] Plaintiffs agree that alleged violations of the Anti-Kickback Statute ("AKS") are not predicate acts that can support a RICO claim. *See* RICO MTD at 36-39; Opp. at 24. Thus, plaintiffs' allegations regarding AKS violations provide no support for, and are irrelevant to, their RICO claims.

C. Plaintiffs Fail to Plead a Valid RICO Enterprise

Plaintiffs recognize that they must plausibly allege that the members of each supposed manufacturer–PBM enterprise (1) shared a common purpose, and (2) conducted the enterprise's—as opposed to their own—affairs. Opp. at 42-43, 47. Their allegations do not satisfy either requirement.

1. Plaintiffs' Concession that PBMs' Favoritism Alternated Between Defendants Undermines Any "Common Purpose"

Plaintiffs theorize two purposes supposedly shared by the members of each alleged enterprise. Neither withstands scrutiny.

Deriving "Secret Profits." Plaintiffs have not pleaded facts showing that each manufacturer united with each PBM for the common purpose of "deriving secret profits" from sales of that manufacturer's products. FAC ¶ 301; *see* Opp. at 44-45. To the contrary, plaintiffs now concede that the six alleged enterprises "alternated" in and out of existence based on "which [manufacturer] held the preferred position on each of the PBM's formularies" at a given time. Opp. at 46. Plaintiffs cannot plead a *common* purpose between each defendant and PBM when each PBM alternately favored different defendants.

Moreover, plaintiffs' opposition confirms that the alleged enterprises represented nothing more than routine business relationships in which each entity pursued *its own* interests. As plaintiffs acknowledge, the PBMs use their formularies to "push significant portions of the consumer market towards (or away

from) particular drugs." Opp. at 11 (citing FAC ¶ 4). Thus, each PBM's objective is to generate the largest profit *for itself*, by giving preferred placement to the drug of the manufacturer that pays the largest rebate. *Id.* at 2; *see also* FAC ¶ 7.

A manufacturer's purpose, by contrast, is to minimize the rebates that it must pay to PBMs for favorable formulary placement. Thus, plaintiffs' insistence that it is in a manufacturer's interest "to sell analog insulins at artificially inflated AWPs *to increase rebate size*" is not plausible. Opp. at 45 (emphasis added). It is plainly not in a manufacturer's interest to pay any higher rebate than is necessary for favorable placement. Thus, plaintiffs' own allegations confirm that the supposed enterprises lack a *common* purpose.

The decisions on which plaintiffs rely do not help them establish a common purpose. In *In re Insurance Brokerage Antitrust Litigation*, 618 F.3d 300 (3d Cir. 2010), the court recognized a common purpose where insurers allegedly submitted "purposefully uncompetitive" bids to a broker "on the understanding that the other insurers would later reciprocate." *Id.* at 336, 375-76. And in *AWP*, the drug manufacturers allegedly conspired with PBMs to report AWPs that were "deliberately set far above" the actual prices at which the drugs were available. Am. Master Consol. Compl. ¶ 3, *AWP*, MDL No. 1456 (D. Mass. July 28, 2003), ECF 443-2. Unlike in those cases, plaintiffs here plead facts showing that the rebates were the product of contentious competitive negotiations between the

manufacturers and the PBMs (FAC ¶ 241), and indeed, plaintiffs expressly *disclaim* any conspiracy between defendants. Opp. at 4, 51.[14]

"Perpetuating" Benchmark Prices. Plaintiffs fare no better with their asserted common purpose of "perpetuating use of insulin benchmark prices as the basis for consumer cost-sharing and out-of-pocket payments." FAC ¶ 304. Plaintiffs' only defense of that theory is to quote their own allegations, which recognize that PBMs and insurers, and not manufacturers, set the terms for cost-sharing. Opp. at 46-47 (quoting FAC ¶ 254).

Plaintiffs cannot plausibly explain how or why manufacturers would perpetuate the use of benchmark prices to set consumer payments. The complaint does not allege that consumer out-of-pocket costs—or the manner in which they are calculated—have any impact on defendants' efforts to secure favorable formulary access. To the contrary, the complaint recognizes the "entrenched" and "historical use of AWP by all industry participants." FAC ¶ 179; *see also id.* ¶ 177. Those are the reasons—and not any enterprise involving manufacturers—

[14] Plaintiffs argue that "the linkages between each PBM and each defendant manufacturer were contractually [sic] and systematic." Opp. at 46. While alleged linkages may be relevant to the *separate* requirement of "relationships among those associated with the enterprise," "an association-in-fact enterprise *must* have" *both* a common purpose *and* relationships. *Boyle v. United States*, 556 U.S. 938, 946 (2009). Further, alleged enterprises that alternate, based on which drug gets preferred placement, would lack the "longevity sufficient to permit [the members] to pursue the enterprise's purpose." *Id.*

that "the most commonly and continuously used set of reference prices in reimbursement and provider payment calculations and negotiations remains AWP." *Id.* ¶ 178.

2. The Complaint Fails to Plausibly Allege that Defendants Conducted the Alleged Enterprises' Affairs

Plaintiffs also fail to plausibly allege that defendants conducted each supposed enterprise. Plaintiffs invoke *Insurance Brokerage* for the proposition that this requirement is satisfied where enterprise members "band together to commit violations they cannot accomplish alone." Opp. at 48 (quoting *Ins. Brokerage*, 618 F.3d at 378). But as the Seventh Circuit explained in *United Food & Commercial Workers Unions & Employers Midwest Health Benefits Fund v. Walgreen Co.*, 719 F.3d 849 (7th Cir. 2013)—which, plaintiffs recognize, aligns with *Insurance Brokerage* (Opp. at 49)—this "band[ing] together" must go beyond the cooperation inherent in the alleged enterprise members' "normal commercial relationships." 719 F.3d at 856. Otherwise, any entity in a commercial relationship could be said to be conducting a RICO enterprise.

The "banding together" test was satisfied in *Insurance Brokerage* because the defendant insurers allegedly colluded with one another—conduct that went far beyond the bounds of normal insurer–broker relations. 618 F.3d at 378. By contrast, the test was *not* satisfied in *Walgreen*, where a pharmaceutical manufacturer allegedly worked with a pharmacy chain to fraudulently fill certain

prescriptions. Although the plaintiffs alleged extensive coordination between the two entities, this "cooperation describes virtually every prescription pharmaceutical distribution chain" and was not enough to plausibly suggest that the defendants were conducting a RICO enterprise. 719 F.3d at 856.

This case clearly falls on the *Walgreen* side of the line. Plaintiffs recognize that the payment of rebates, in exchange for preferred formulary placement, is "legitimate." FAC ¶ 6. And they acknowledge that PBMs award preferred placements to manufacturers offering the most favorable terms. Opp. at 46. Plaintiffs thus fail to allege any cooperation beyond "that inherent in every commercial transaction" between a drug manufacturer and PBM. *Walgreen*, 719 F.3d at 856. This basic cooperation does not plausibly suggest that defendants conducted any enterprise.

D. Plaintiffs Do Not Adequately Plead Proximate Causation

To satisfy RICO's proximate cause requirement, plaintiffs must allege that "there are no independent factors that account for [their] injury." *Bridge*, 553 U.S. at 658. Here, plaintiffs' complaint shows that consumers' out-of-pocket costs are determined by multiple independent decisions that defendants do not control. These include: (i) the price a pharmacy charges at the point-of-sale, (ii) the amounts that the insurer requires the consumer to pay out-of-pocket, and (iii) whether the insurer reduces the consumer's out-of-pocket payment based on

the rebate that the manufacturer pays to the insurer or its PBM. FAC ¶¶ 169, 179, 181-196. These independent third-party decisions foreclose plaintiffs' RICO claims. RICO MTD at 48-51; *see also Anza*, 547 U.S. at 459 (no proximate causation because some of plaintiff's damages "could have resulted from factors other than [defendants'] alleged acts of fraud").

Plaintiffs concede that pharmacies and health insurers determine plaintiffs' out-of-pocket payments for analog insulin. Opp. at 8-9. But plaintiffs insist that they were directly injured by defendants because those third parties use benchmark prices to calculate out-of-pocket payments. *Id*. at 8-9, 42. Plaintiffs do not allege, however, that any pharmacies or health insurers used defendants' benchmark prices *because of defendants' alleged misrepresentations*. To the contrary, plaintiffs insist that "many" of the health insurers "knew the defendants' benchmark prices were false benchmarks." *Id.* at 37.

That admission is fatal to plaintiffs' claims. While *Bridge* and *Avandia* show that intervening third-party decisions may not *per se* negate proximate causation, plaintiffs must establish that decisions by third parties *resulted from* defendants' alleged fraud. *See Bridge*, 553 U.S. at 658-59 (reasoning that chain of causation would be broken if third party took actions that injured plaintiffs despite knowing defendants' statements were false); *Avandia*, 804 F.3d at 636-37, 644-45 (rejecting argument that physicians' decisions to prescribe Avandia broke chain of

causation, where plaintiffs alleged that physicians relied on defendant's misrepresentations in making that decision). Absent such allegations, plaintiffs' claims raise the very concerns articulated in *Holmes*: It is impossible to ascertain or apportion damages attributable to defendants' alleged misconduct as opposed to the independent, unrelated decisions of pharmacies and health insurers.[15]

Faced with this glaring defect, plaintiffs turn yet again to *Lupron* and *AWP*. But the proximate causation reasoning in those decisions does not survive more recent Supreme Court precedent. In *Lupron*, the court rejected the defendants' argument that the chain of causation was broken by the intervening acts of physicians (as prescribers and providers), publishers of price compendia, and payors. *See* 295 F. Supp. 2d at 175. The court reasoned that those acts were foreseeable to the defendant manufacturers: "What that argument ignores is the corollary requirement that the intervening act be unforeseeable and completely independent of any act undertaken by the original actor." *Id*. In *AWP*, the court expressly relied on the *Lupron* court's reasoning regarding foreseeability. *See* 307

[15] Consistent with their theory of fraud, plaintiffs suggest that the appropriate measure of damages is the difference between AWPs and "net prices." Opp. at 37. But that is nonsensical: Pharmacies typically charge consumers *less than* the published AWP (e.g., AWP-18%), and consumers often pay only a portion of the charge (coinsurance). *See* Opp. at 8-9; FAC ¶¶ 179, 181-196; *see also*, *e.g.*, FAC ¶¶ 87-102 (plaintiffs "consistently" reach a point where they "must pay 40% of the cost" of analog insulin).

F. Supp. 2d at 207-08.

In *Hemi Group, LLC v. City of New York*, 559 U.S. 1 (2010), however, the Supreme Court rejected the relevance of foreseeability to proximate causation under RICO. *Id.* at 12. The Court criticized the argument that "RICO's proximate cause requirement [should] turn on foreseeability, rather than on the existence of a sufficiently 'direct relationship' between the fraud and the harm." *Id.* It observed: "Our precedents make clear that in the RICO context, the focus is on the directness of the relationship between the conduct and the harm. Indeed, *Anza* and *Holmes* never even mention the concept of foreseeability." *Id.*; *see also id.* at 10 (a "direct relationship" usually does not exist "beyond the first step" of a causal chain).

Lupron and *AWP* are distinguishable for two additional reasons. First, the health insurers themselves brought suit, alleging that they were deceived by AWPs that did not actually reflect the prices paid by providers (pharmacies and physicians).[16] *AWP*, 307 F. Supp. 2d at 201 & n.1; *Lupron*, 295 F. Supp. 2d at 159-61. Here, by contrast, there is no allegation that health insurers were deceived into using defendants' benchmark prices to set consumers' out-of-pocket

[16] *AWP* also included claims by Medicare Part B beneficiaries, who alleged that their out-of-pocket payments were based on defendants' fraudulent AWPs. 307 F. Supp. 2d at 201. But Medicare Part B out-of-pocket payments are tied to AWP by statute, and are not affected by the independent decisions of third-party pharmacies and health insurers.

payments.

Second, the plaintiffs' injuries in *Lupron* and *AWP* reflected the very purpose of the scheme: The defendants inflated AWPs in order to cause the plaintiffs to increase their reimbursements to providers, thereby incentivizing providers to use the defendants' drugs. *AWP*, 307 F. Supp. 2d at 207-08; *Lupron*, 295 F. Supp. 2d at 175. Here, plaintiffs do not allege that defendants intended or benefited from the increase in consumers' out-of-pocket payments. To the contrary, plaintiffs allege that defendants intended "to influence the PBMs' formulary decisions"—not consumers' out-of-pocket payments—by increasing their rebate payments to PBMs. *See, e.g.*, FAC ¶¶ 2, 10, 180, 204-207. Plaintiffs further allege that defendants' "net prices" remained constant (FAC ¶¶ 2, 206, 243, 306), confirming that defendants *did not benefit* from any increases in out-of-pocket payments by consumers. Thus, this case lacks the direct nexus between the alleged scheme and the purported injuries that animated the AWP cases. *Cf. Avandia*, 804 F.3d at 645 (finding proximate causation because defendants' "fraudulent scheme could have been successful only if plaintiffs" suffered the "very injury" for which they seek recovery).[17]

[17] Plaintiffs suggest that because pharmacies and insurers use AWPs as a starting point for calculating consumers' out-of-pocket costs, consumers would save "millions" if AWPs reflected the manufacturer's "net prices" rather than the price paid by pharmacies. Opp. at 40-42. But AWP is used as a starting point for

E. Plaintiffs Do Not Adequately Plead a RICO Conspiracy

Plaintiffs attempt to rescue their RICO conspiracy claim by rewriting it, but to no avail. In the complaint, plaintiffs allege a conspiratorial agreement between defendants: "The Defendant Drug Manufacturers have violated § 1962(d) by agreeing and conspiring to violate 18 U.S.C. § 1962(c)." FAC ¶ 348; *see also id.* ¶ 355 (asserting joint and several liability). But now, plaintiffs contend that they are alleging "six conspiracies . . . between each of the two defendants and each of the three PBMs, *not* between the defendants." Opp. at 51. That conspiracy claim, however, appears nowhere in the complaint. Plaintiffs' need to reengineer the structure of the supposed RICO conspiracy confirms the infirmity of their claim.

Even if plaintiffs *had* alleged six manufacturer-PBM conspiracies, their section 1962(d) claim still would fail.

First, plaintiffs acknowledge that their conspiracy claim must be dismissed if they do not adequately allege an endeavor that, if completed, would constitute a substantive RICO violation. Opp. at 50-51 (citing, e.g., *Salinas v. United States*, 522 U.S. 52, 65 (1997)). Because plaintiffs' substantive RICO claim fails for the reasons set forth above, their tagalong conspiracy claim necessarily fails, too.

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the prices charged by pharmacies precisely because of its relationship to the prices that pharmacies pay for drugs. *See* FAC ¶¶ 175-177. If AWPs suddenly reflected "net prices," there is no reason (and plaintiffs provide none) to believe it would still be used to set the point-of-sale prices charged by pharmacies to consumers.

Second, plaintiffs fail to satisfy *Twombly*'s rule that "an allegation of parallel conduct and a bare assertion of conspiracy will not suffice" to set forth a conspiracy claim. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556-57 (2007). A plaintiff must instead place such allegations "in a context that raises a suggestion of a preceding agreement, not merely parallel conduct that could just as well be independent action." *Id.* at 557. Even if plaintiffs' manufacturer-PBM enterprises could be construed as conspiracies, plaintiffs have not put forth any facts plausibly suggesting that each pairing agreed to facilitate a racketeering scheme through a RICO enterprise. Their allegations are instead entirely consistent with the "independent action" (*see id.*) of each manufacturer offering the most favorable rebate it can justify and each PBM awarding preferred placements after seeing how the competing manufacturers' offers stack up. Without any allegations—let alone plausible ones—of an agreement to violate RICO, plaintiffs' conspiracy claim fails.

II. The New Jersey Consumer Fraud Act Claims Should Be Dismissed

As demonstrated in defendants' opening brief, plaintiffs' NJCFA claims should be dismissed because plaintiffs have not alleged any "unlawful conduct" by defendants or any "ascertainable loss" suffered. RICO MTD at 55-60.

A. Plaintiffs Have Not Alleged Unlawful Conduct Under the NJCFA

Plaintiffs have failed to allege a fraudulent or deceptive practice under the NJCFA. As plaintiffs acknowledge, the "central element [of a deceptive practice] is the capacity to mislead." Opp. at 52 (emphasis omitted). But the mere act of "publishing . . . analog insulin" list prices—which is done by third-party price reporting companies, not the defendant manufacturers—does not amount to such a deceptive practice for the reasons described above. *See supra* at 9-17.

Further, under New Jersey law, a fully disclosed list price—even an allegedly "excessive" one—is not deceptive as a matter of law. *See, e.g.*, *Quigley v. Esquire Deposition Servs., LLC*, 975 A.2d 1042, 1048 (N.J. Super. Ct. App. Div. 2009) ("Sellers of goods and services generally may charge whatever the market will bear so long as they do not engage in deceptive or other unfair sales practices."); *see also Ciser v. Nestle Waters N. Am. Inc.*, 596 F. App'x 157, 161, 164 (3d Cir. 2015) (affirming district court's holding that a "fully disclosed late fee" does not evince a "capacity to mislead" in NJCFA case).

Plaintiffs have also failed to state a claim for an "unconscionable" practice under the NJCFA. As set out in defendants' opening brief, courts have uniformly rejected claims of unconscionability based solely on "excessive" prices. RICO MTD at 56; *see also, e.g.*, *Quigley*, 975 A.2d at 1048 (explaining that the

"consumer fraud" in *Kugler v. Romain*[18] "did not consist solely of a seller charging a consumer an allegedly excessive price," but involved "numerous misrepresentations," "various other deceptive practices," and sales of "practically worthless" products). In response, plaintiffs recite generic standards for "unconscionability," but do not identify *any* case in which a court found allegedly excessive pricing to be "unconscionable" absent allegations of affirmative deception concerning the terms or conditions of sale or the value of a product.[19] In the absence of allegations other than purportedly excessive pricing, plaintiffs' claim should be dismissed.

B. Plaintiffs Have Failed to Allege an Ascertainable Loss

Defendants' opening brief demonstrated that plaintiffs cannot satisfy the NJCFA's "ascertainable loss" requirement under *any* recognized theory of loss. *See* RICO MTD at 57-60. Plaintiffs cannot plausibly allege an ascertainable loss under the NJCFA based on a theory that the insulin they received was "essentially worthless," because their complaint acknowledges that they received analog insulin in exchange for a payment. *See, e.g.*, FAC ¶¶ 21-156. Nor can they rely on

[18] 279 A.2d 640 (N.J. 1971); *see also* Opp. at 53, 55 n.166 (citing *Kugler*).

[19] The primary case on which plaintiffs rely, *Cottrell v. Alcon Labs.*, 874 F.3d 154 (3d Cir. 2017), is inapposite. The sole question in that case was whether plaintiffs had alleged an "injury in fact" sufficient to confer Article III standing, and the court emphasized that it did not reach the sufficiency of plaintiffs' claims under Rule 12(b)(6). *Id.* at 161.

the "benefit of the bargain" theory, because the complaint neither identifies any "reasonable belief . . . induced by a misrepresentation" about analog insulins nor alleges a quantifiable "difference in value between the [insulin] promised and the [insulin] received." RICO MTD at 57-58 (citing *In re Gerber Probiotic Sales Practices Litig.*, 2014 WL 3446667, at *3 (D.N.J. July 11, 2014)).

Rather than clarify their theory of loss, plaintiffs reiterate the conclusory assertion that "'the difference in value between the product promised and the one received' is the difference between the defendants' AWPs for analog insulins and a reasonable approximation of their true net prices." Opp. at 56. But plaintiffs fail to explain why they should be entitled to the lowest available price in the pharmaceutical distribution chain. Moreover, plaintiffs have not identified *any* difference in value between the analog insulins they were promised and the analog insulins they received.[20] Nowhere in the complaint or opposition do plaintiffs

[20] Cases in which courts have found adequate allegations under the "benefit of the bargain theory"—including plaintiffs' cases—involve allegations of a concrete disparity between the product as advertised and as sold. *See, e.g.*, *Dzielak v. Whirlpool Corp.*, 26 F. Supp. 3d 304, 335-36 (D.N.J. 2014) (plaintiffs alleged ascertainable loss in the amount of "the price premium paid, plus increased energy costs over the lifetime of the appliance" due to their purchases of washing machines falsely advertised as "Energy Star-compliant"); *Smajlaj v. Campbell Soup Co.*, 782 F. Supp. 2d 84, 99 (D.N.J. 2011) (plaintiffs alleged ascertainable loss of the "difference in retail price between what they paid for (less-sodium soup) and what they got (soup equivalent for their purposes to regular tomato soup)").

contend that the analog insulins they purchased failed to perform as anticipated or conform to their expectations. Instead, plaintiffs allege that they received exactly the insulin they expected, but at a higher price than they would have liked to pay had they realized that the manufacturer's net recovery would be much lower than the purchase price. But the difference between these figures—and the difference between a price paid by a consumer and the price that the consumer would like to pay—is not an "ascertainable loss."[21]

III. All of Plaintiffs' State Law Claims Should Be Dismissed

Defendants' opening brief demonstrated that all of plaintiffs' state law claims should be dismissed for five independent reasons:

First, all of the state law claims should be dismissed for the fundamental reason that none of the complaint's allegations "come close to plausibly suggesting that defendants have done anything fraudulent, unfair, or unconscionable." State MTD at 1, 4-5;[22] *see also* RICO MTD at 26-54. Plaintiffs' response relies entirely on their contention that they have stated claims under RICO and the NJCFA (*see* Opp. at 59), and should be rejected for the reasons explained above.

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[21] In addition, plaintiffs' NJCFA claims should be dismissed under Rule 9(b). *See* RICO MTD at 54-55.

[22] "State MTD" refers to Defendants' Memorandum of Law in Support of Motion to Dismiss the First Amended Class Action Complaint (Counts 6-59) (Dkt. #158-2).

Second, the state law claims should be dismissed because the complaint merely offers threadbare recitations of the statutes. State MTD at 5-6. Plaintiffs' contention that the complaint satisfactorily pleads these claims because it sets out "all the [legal] elements of each state-law claim" (Opp. at 61) is irrelevant. As explained by the cases cited in defendants' opening brief, "allegations that are no more than legal conclusions" are inadequate. State MTD at 5-6 (citing *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 2017 WL 4642285, at *14 (E.D. Pa. Oct. 17, 2017)).[23] And plaintiffs' assertion that their state law counts "explain in detail how the defendants violated the statute at issue" (Opp. at 61) is belied by the complaint, which attempts to support the state law claims by relying generally on "conclusory allegations . . . regarding defendants' alleged conduct" and incorporating by reference the previous allegations "without adding further detail." State MTD at 7-8 (discussing FAC ¶¶ 407-866); *see also Hughes v. Panasonic Consumer Elecs. Co.*, 2011 WL 2976839, at *17 (D.N.J. July 21, 2011) (dismissing claims under state consumer protection laws because

[23] Plaintiffs suggest that *In re Suboxone* is "inapposite," but they ignore the case's holding that plaintiffs must do more than "follow[] the same format of repeat[ing] and realleg[ing] every preceding allegation and then adding the conclusory statement that [the] aforementioned practices by Defendants[] are in violation of a particular state law," as doing so fails to explain how the listed statutes "apply to the facts of this case." 2017 WL 4642285, at *13 (citations and internal quotation marks omitted).

"general allegations of statutory violations and conclusory citations to other states' statutes do not meet the most elementary pleading requirements").

Third, every state law requires a plaintiff to allege proximate causation, a requirement that plaintiffs have utterly failed to satisfy. State MTD at 6-7; *see also Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912, 934 & n.17 (3d Cir. 1999) (holding that RICO and state-law claims both require proximate causation). Plaintiffs do not even mention the cases cited by defendants, instead arguing that they have adequately alleged proximate causation for their RICO claims and can "meet the state-law proximate cause requirements just as they meet RICO's." Opp. at 61-62. Because plaintiffs' RICO claims fail for lack of proximate causation (*see supra* at 22-26), their state law claims fail as well.

Fourth, the state law claims are all based on the same underlying allegations of fraudulent conduct, and thus should be dismissed under Rule 9(b). State MTD at 7-8. Plaintiffs' only response is that Rule 9(b) "does not apply to . . . claims of unconscionable or unfair practices." Opp. at 61 n.190. That assertion is belied by *DeGennaro v. American Bankers Insurance Co. of Florida*, in which this Court dismissed state law claims—including one alleging an "unconscionable" violation of the NJCFA—for failing to satisfy Rule 9(b). 2017 WL 2693881, at *5, *10-11 (D.N.J. June 22, 2017) (Martinotti, J.). Indeed, "a plaintiff cannot escape Rule 9(b)

by alleging claims that do not traditionally involve fraud; rather, the test is whether the particular claim alleged in [a] matter sounds in fraud." *Gray v. Bayer Corp.*, 2009 WL 1617930, at *2 (D.N.J. June 9, 2009). Thus, in *Gray*, the court rejected plaintiff's argument that Rule 9(b) should not apply because her claim was for an "unconscionable commercial practice," insofar as the "underpinning" of the claim was fraud. *See id.* Likewise, plaintiffs' state law claims all sound in fraud because they all rely on the underlying allegation that defendants "misrepresented their AWPs as benchmark prices when they were not." Opp. at 17; *see also id.* at 21, 24, 27, 30, 32, 53 (same).[24] Indeed, plaintiffs concede that "*all* [of their] federal and state-law causes of action" are based "on the same claim that Novo and Sanofi deceived them into overpaying for insulin." *Id.* at 66.

Fifth, the state law claims should be dismissed because plaintiffs have not provided the Court with any basis for determining a "fair price" for insulin products, and thus plaintiffs' alleged damages are speculative. State MTD at 8-9. Plaintiffs' opposition relies on inapposite cases dealing with third-party payors ("TPPs") who alleged that they overpaid for drugs because a defendant's

[24] *Plumbers' Local Union No. 690 Health Plan v. Sanofi, S.A.* is of no help to plaintiffs, as the court held that Rule 9(b) rather than Rule 8 applied to "plaintiffs' state law consumer protection and unfair practice claims . . . [t]o the extent the scheme rests on falsehoods or misrepresentations—*e.g.*, about the true price of the drugs." 2017 WL 1822277, at *6 (D.N.J. May 4, 2017) (citation and internal quotation marks omitted).

misrepresentations led them to put the defendant's drugs, rather than lower-priced generic drugs, on their formularies. *See In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 531 (3d Cir. 2004) (explaining that TPPs "suffered direct economic harm when, as a result of [defendant's] alleged misrepresentations, they paid supracompetitive prices for [a drug] instead of purchasing lower-priced generic [drugs]"); *Avandia*, 804 F.3d at 636, 639-40 (relying on *Warfarin*); *see also Teamsters Local 237 Welfare Fund v. AstraZeneca Pharm. LP*, 136 A.3d 688, 696-97 & n.34 (Del. 2016) (rejecting argument based on *Avandia* and noting that plaintiffs' theory—that they "would have paid a lower 'market' price" for drugs if they had not been misled—"has been rejected by other courts as speculative because it does not represent the realities of the pharmaceutical market").[25]

IV. Certain State Law Claims Should Be Dismissed for Independent Reasons

Defendants also established that certain state law claims should be dismissed for a number of independent reasons.

[25] Plaintiffs' assertion that their damages are "readily quantifiable" via expert testimony (Opp. at 56-57) is without basis and cannot justify proceeding to discovery. And plaintiffs' vague assertion that the cases cited in defendants' opening brief are "inapt" (*id*. at 62 n.194) simply ignores the relevant holdings of those cases. *See, e.g.*, *Prohias v. Pfizer, Inc.*, 485 F. Supp. 2d 1329, 1337 (S.D. Fla. 2007) (holding that "[d]etermination of [a] *hypothetical* price [for a drug], even with expert proof, is too speculative to be the premise of an 'actual injury'").

First, the Court should dismiss the claims brought under the laws of states in which no named plaintiff resides or is alleged to have made a purchase. State MTD at 9-11; *see also id.* App'x A. Because "class representatives must meet Article III standing requirements the moment a complaint is filed," this lack of standing is fatal to plaintiffs' claims under the laws of seventeen states. *Id.* at 10 (quoting *Neale v. Volvo Cars of N. Am.*, *LLC*, 794 F.3d 353, 367 (3d Cir. 2015)).

In response, plaintiffs concede that in a purported class action, only the named parties are relevant to Article III standing. Opp. at 64-65. As the Supreme Court has explained, "[t]hat a suit may be a class action . . . adds nothing to the question of standing." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 n.6 (2016). Thus, "even named plaintiffs who represent a class must allege and show that they personally have been injured, not that injury has been suffered by other, unidentified members of the class to which they belong." *Id*. (internal quotation marks omitted).

Despite their concession, plaintiffs make no attempt to prove that they have standing to assert claims in the states in which they neither reside nor have purchased defendants' analog insulins. Instead, plaintiffs suggest that the Third Circuit's affirmance of the certification of a multi-state settlement class in the *Prudential Insurance* litigation relieves them of the burden of establishing standing to bring claims in other states. Opp. at 63-65 (citing *In re Prudential Ins. Co. Am.*

Sales Prac. Litig. Agent Actions, 148 F.3d 283 (3d Cir. 1998)). Plaintiffs' suggestion is directly contrary to the Supreme Court's holding in *DaimlerChrysler Corp. v. Cuno* that "a plaintiff must demonstrate standing for each claim he seeks to press." 547 U.S. 332, 352 (2006); *accord Neale*, 794 F.3d at 359; *Dzielak*, 26 F. Supp. 3d at 332 n.18.

Plaintiffs try to distinguish *DaimlerChrysler* by arguing that it "was not a class action." Opp. at 65 (emphasis omitted). But that argument ignores that class allegations "add[] nothing to the question of standing." *Spokeo*, 136 S. Ct. at 1547 n.6; *see also Dzielak*, 26 F. Supp. 3d at 332 n.18. Thus, allegations asserted on behalf of absent class members, particularly where the putative class has not been certified, cannot cure the named plaintiffs' lack of standing. Further, if a named plaintiff in a class action did not have to establish standing for each claim, then "a 'plaintiff would be able to bring a class action complaint under the laws of nearly every state in the Union without having to allege concrete, particularized injuries relating to those states, thereby dragging defendants into expensive nationwide class discovery, potentially without a good-faith basis.'" *Dzielak*, 26 F. Supp. 3d at 332 n.18 (quoting *In re Magnesium Oxide Antitrust Litig.*, 2011 WL 5008090, at *10 (D.N.J. Oct. 20, 2011)).[26]

[26] *See also*, *e.g.*, *McGuire v. BMW of N. Am., LLC*, 2014 WL 2566132, at *6 (D.N.J. June 6, 2014) (same); *In re Ductile Iron Pipe Fittings (DIPF) Indirect*

Plaintiffs also try to avoid *DaimlerChrysler*'s requirement that they plead standing for "each claim" by insisting that they assert only one claim—i.e., that they "base *all* [of their] federal and state-law causes of action on the same claim that Novo and Sanofi deceived them into overpaying for insulin." Opp. at 66. This again directly contradicts *DaimlerChrysler*, in which the Supreme Court rejected the argument that standing to assert one claim suffices to establish standing over all claims "arising from the same 'nucleus of operative fact.'" 547 U.S. at 352-53; *see also Neale*, 794 F.3d at 359 ("Thus, we do not exercise jurisdiction over one claim simply because it arose "from the same 'nucleus of operative fact'" as another claim.") (citing *DaimlerChrysler*, 547 U.S. at 352).[27]

Second, for each state as to which no plaintiff is alleged to have purchased relevant products from one of the defendants, the Court lacks subject matter jurisdiction to adjudicate claims under that state's law against that particular defendant. State MTD at 11-13. Plaintiffs ignore this Court's precedent, which permits "putative class action plaintiffs [to] bring class claims based on products

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Purchaser Antitrust Litig., 2013 WL 5503308, at *11-12 (D.N.J. Oct. 2, 2013) (same).

[27] The approach taken by the two district court cases cited by plaintiffs (Opp. at 65 n.206) has been expressly rejected by several recent decisions from this district, and neither so much as mentions *DaimlerChrysler*. *See, e.g.*, *McGuire*, 2014 WL 2566132, at *6 (acknowledging *Ramirez v. STI Prepaid LLC*, 644 F. Supp. 2d 496 (D.N.J. 2009) but finding its reasoning unpersuasive).

they did not purchase" *only* if plaintiffs' claims "all target the same [d]efendant." *In re L'Oreal Wrinkle Cream Mktg. & Sales Practices Litig.*, 2013 WL 6450701, at *4 (D.N.J. Dec. 9, 2013). The decisions that plaintiffs invoke—which all addressed claims involving products manufactured or distributed by the same defendant—simply reflect this rule.[28]

Third, eight claims fail due to statutory bars on class actions pursuant to Justice Stevens' controlling opinion in *Shady Grove Orthopedic Associates, P.A. v. Allstate Insurance Co.*, 559 U.S. 393 (2010). State MTD at 13-14. Plaintiffs' response relies on a misreading of *Knepper v. Rite Aid Corp.*, 675 F.3d 249 (3d Cir. 2012). Opp. at 68. *Knepper* addressed the narrow (and unrelated) issue of whether "the Rules Enabling Act . . . bar[s] certification of an opt-out class action

[28] *Marcus v. BMW of North America, LLC* did not hold that plaintiffs who did not purchase a product from a defendant may nonetheless sue that defendant based on their purchase of another defendant's products, as plaintiffs suggest. *See* 687 F.3d 583, 599 (3d Cir. 2012) (holding that a plaintiff who leased one model of BMW with one kind of Bridgestone RFT tire could satisfy Rule 23's typicality requirement for claims involving "all 2006-2009 BMW vehicles equipped with Bridgestone RFTs"). Plaintiffs' other cases are likewise inapposite. *See Riaubia v. Hyundai Motor Am.*, 2017 WL 3602520, at *1-2 (E.D. Pa. Aug. 22, 2017) (plaintiff who purchased one model of Hyundai had standing to sue Hyundai on behalf of purchasers of "various Hyundai models equipped with the same allegedly defective . . . feature"); *Neuss v. Rubi Rose, LLC*, 2017 WL 2367056, at *2, *6 (D.N.J. May 31, 2017) (plaintiff who bought one product from defendants had standing as to other products manufactured by same defendants); *Cannon v. Ashburn Corp.*, 2016 WL 7130913, at *1, *4 (D.N.J. Dec. 7, 2016) (plaintiffs had standing as to bottles of wine they did not purchase because all claims were against the same wine-selling website).

based on state employment-law claims paralleling the FLSA," and concluded that under *either* Justice Stevens's *Shady Grove* concurrence or Justice Scalia's plurality opinion, such an opt-out action would not violate the Rules Enabling Act, without deciding which *Shady Grove* opinion is controlling. 675 F.3d at 264-65. *Knepper* thus did not state which of the *Shady Grove* opinions should be applied by lower courts in *any* context, much less the context of state consumer law bars on class actions. Indeed, courts in this circuit have recognized, after *Knepper*, that Justice Stevens's concurrence is controlling. *See Davis v. Ace Hardware Corp.*, 2014 WL 688132, at *8 n.10 (D. Del. Feb. 21, 2014) (collecting cases and noting that *Knepper* did not "discuss[] which [*Shady Grove*] opinion is controlling"). And courts applying Justice Stevens's concurrence have routinely held that class-action bars in state statutes provide a procedure "so bound up with the state-created right or remedy that [they] define[] the scope of that substantive right or remedy and so displace[] Rule 23." *See, e.g.*, *Delgado v. Ocwen Loan Servicing, LLC*, 2017 WL 5201079, at *9 (E.D.N.Y. Nov. 9, 2017) (collecting cases) (internal quotation marks omitted).[29]

[29] Neither of the district court cases cited by plaintiffs (both of which are from the same judge) so much as cite *Knepper*, much less treat it as "binding Third Circuit precedent" (Opp. at 68) on this issue. *See In re Volkswagen Timing Chain Prod. Liab. Litig.*, 2017 WL 1902160, at *24 (D.N.J. May 8, 2017) (relying on an out-of-circuit district court case and an Eleventh Circuit case); *In re Liquid*

Fourth, six claims fail due to plaintiffs' lack of privity with defendants. State MTD at 14-15. Plaintiffs have conceded that their Kentucky claim should be dismissed on this ground. Opp. at 69. In addition, the Arizona,[30] District of Columbia,[31] Idaho,[32] and Vermont[33] claims fail due to those statutes' privity

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Aluminum Sulfate Antitrust Litig., 2017 WL 3131977, at *25 (D.N.J. July 20, 2017) (citing no authority for its interpretation of *Shady Grove*).

[30] Courts have declined to "extend[] the private cause of action under the [Arizona statute] to subsequent purchasers," because such purchasers are not parties "to the original transaction." *Sullivan v. Pulte Home Corp.*, 290 P.3d 446, 454 (Ariz. Ct. App. 2012), *vacated in part on other grounds by* 306 P.3d 1 (Ariz. 2013). Indeed, in the appeal of the case cited by plaintiffs (*see* Opp. at 70 n.228), the Ninth Circuit affirmed summary judgment against the plaintiff because she failed to raise a factual dispute "as to whether [defendant] was a party to the sale of a vehicle to [plaintiff]." *J-Hanna v. Enterprise Rent-A-Car Co. of S.F., LLC*, 672 F. App'x 737, 737 (9th Cir. 2017) (citing *Sullivan*, 290 P.3d at 454-55).

[31] The District of Columbia's highest court has held that "it is the ultimate retail transaction between the final distributor and the individual member of the consuming public that the [statute] covers." *Adam A. Weschler & Son, Inc. v. Klank*, 561 A.2d 1003, 1005 (D.C. 1989); *see also In re Cast Iron Soil Pipe & Fittings Antitrust Litig.*, 2015 WL 5166014, at *30 (E.D. Tenn. June 24, 2015) (following *Weschler* and holding that indirect purchasers "are not consumers within the meaning of the [D.C. statute]").

[32] The Idaho Supreme Court has held that privity is required under the Idaho statute. *See Duspiva v. Fillmore*, 293 P.3d 651, 660 (Idaho 2013) ("In order to have standing under the [Idaho statute], the aggrieved party must have been in a contractual relationship with the party alleged to have acted unfairly or deceptively.") (citation omitted).

[33] Courts have dismissed claims under Vermont's consumer protection law on this ground. *See In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2015 WL 5458570, at *18 (D. Mass. Sept. 16, 2015) (dismissing Vermont consumer protection claim because plaintiffs "fail to plausibly allege that Defendants sell directly to consumers"); *see also Knutsen v. Dion*, 90 A.3d 866,

requirements.[34]

Fifth, six claims fail because plaintiffs do not plead reliance. State MTD at 15-16. Plaintiffs do not attempt to show that they are *not* required to plead reliance under those statutes. Opp. at 72-73. Instead, they rely entirely on *In re Volkswagen Timing Chain Product Liability Litigation*, in which the court held that the plaintiffs had "sufficiently plead[ed] reliance" because they "successfully ple[aded] actionable misrepresentations." 2017 WL 1902160, at *18, *24. Because plaintiffs (as explained above) have not pleaded facts showing *any* misrepresentation by defendants, *In re Volkswagen* does not help them.

Sixth, plaintiffs' claims fail as to five states whose consumer protection statutes require that "some portion of the defendant's alleged wrongdoing"—e.g., the pricing decisions that are the basis of plaintiffs' claims here—must have occurred within the state. State MTD at 16-17. Plaintiffs' argument relies on the incorrect contention that their *purchases* of insulin products within the states at issue satisfy this requirement. Opp. at 73-76.[35]

871-72 (Vt. 2013) (holding that liability under the Vermont statute requires "direct participation in the unfair or deceptive acts" or "direct involvement in the transaction at issue").

[34] Defendants acknowledge that the Massachusetts claim is not properly dismissible on this ground.

[35] Plaintiffs' attempts to distinguish defendants' cases miss the mark, and their cases do not establish that an in-state purchase is sufficient to satisfy this

Finally, defendants showed that the Mississippi and Ohio claims should be dismissed for failure to comply with procedural requirements. State MTD at 17-18. Plaintiffs' response relies on inapposite cases. Opp. at 76-77.[36]

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requirement. As to Illinois, the "circumstances that relate to the disputed transaction [must] occur primarily and substantially in Illinois" (*De David v. Alaron Trading Corp.*, 2015 WL 2208407, at *5 (N.D. Ill. May 7, 2015)), while plaintiffs' case merely held that although Illinois law applied to a putative class action, the class had been improperly certified under state law. *See Barbara's Sales, Inc. v. Intel Corp.*, 879 N.E.2d 910, 928 (Ill. 2007). As to New Hampshire, the statute requires an "unfair method of competition or unfair or deceptive act or practice which took place within New Hampshire" (*Mueller Co. v. U.S. Pipe & Foundry Co.*, 2003 WL 22272135, at *6 (D.N.H. Oct. 2, 2003)); rather than finding that a mere purchase satisfied this requirement, plaintiffs' case involved a company that "reached into New Hampshire . . . to interfere with a contract" that was executed and partly performed in New Hampshire. *Harbour Capital Corp. v. Allied Capital Corp.*, 2009 WL 2185449, at *6 (D.N.H. July 22, 2009). As to New York, the deceptive act "must occur in New York" under the statute. *Goshen v. Mut. Life Ins. Co. of N.Y.*, 98 N.Y.2d 314, 324-25 (2002); *see also Ward v. TheLadders.com, Inc.*, 3 F. Supp. 3d 151, 167 & n.7 (S.D.N.Y. 2014) (explaining that courts following *Goshen* have held that the statute "requires that the deceptive transaction occur in New York" and that it is not enough that "the victim be deceived while located in New York"). As to Tennessee, plaintiffs cite no case at all, whereas defendants' case clearly states that the Tennessee statute "prohibits only 'acts or practices' occurring within Tennessee's borders." *Encore Med., L.P. v. Jay Kennedy, D.C.*, 2013 WL 839838, at *30 (W.D. Pa. Mar. 6, 2013). And as to Wisconsin, statements must be made "in this state" to give rise to liability under the statute (*Calnin v. Hilliard*, 2008 WL 336892, at *12-13 (E.D. Wis. Feb. 5, 2008)), while plaintiffs' case merely rejects the argument that alleged misrepresentations were non-actionable "puffery" and does not consider the in-state wrongdoing requirement. *In re General Motors LLC Ignition Switch Litig.*, 257 F. Supp. 3d 372, 456-60 (S.D.N.Y. 2017).

[36] As to Mississippi, "failure to satisfy the prerequisite of an attempt at informal dispute resolution [through a settlement program approved by the state attorney general] is fatal" to a claim under the statute. State MTD at 18 n.15

CONCLUSION

For the foregoing reasons, defendants respectfully request that the First Amended Class Action Complaint be dismissed with prejudice.

(citing *Humphrey v. CitiBank NA*, 2013 WL 5407195, at *6 (N.D. Miss. Sept. 25, 2013)). Plaintiffs cite a case addressing the Texas Insurance Code that does not mention the Mississippi statute. *Prado v. Allstate Tex. Lloyd's*, 2016 WL 9414132 (W.D. Tex. Nov. 16, 2016). As to Ohio, plaintiffs ignore the statute's requirement that a complaint must specifically allege rules or judicial decisions under which an alleged practice has been found deceptive, which courts in this district have relied upon to dismiss improperly pleaded Ohio claims. *See Cox v. Chrysler Grp., LLC*, 2015 WL 5771400, at *12 (D.N.J. Sept. 30, 2015) (dismissing Ohio claim on this ground).

Dated: August 20, 2018

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